# **EXHIBIT A**

# UNITED STATES BANKRUPTCY COURT DISTRICT OF MASSACHUSETTS EASTERN DIVISION

In re:

NEW ENGLAND COMPOUNDING PHARMACY, INC., Debtor.

Chapter 11 Case No. 12-19882-HJB

DECLARATION OF MICHAEL F. BARRETT, ESQ. IN SUPPORT OF CONFIRMATION OF FIRST AMENDED JOINT CHAPTER 11 PLAN OF NEW ENGLAND COMPOUNDING PHARMACY, INC. AND FOR APPROVAL OF INSPIRA SETTLEMENT

Michael F. Barrett, Esquire, being of lawful age does set down and state the following:

- of the New England Compounding Pharmacy, Inc. ("NECC") [Docket No. 1054] (as amended at Docket No. 1154 and thereafter, from time to time, and including all exhibits and supplements thereto, the "Plan") and, more specifically, in support of approval of the Inspira Health Network, Inc. ("Inspira") Settlement and Non-Debtor Third Party Release which is a part of the proposed Plan. I am competent to testify under oath to the matters set forth herein if called to do so in that I chaired the committee comprised of New Jersey claimant lawyers, members of the Official Creditors' Committee ("OCC"), members of the Plaintiffs Steering Committee ("PSC") of the NECC Products Liability Multi-District Litigation ("MDL"), the NECC Trustee, Paul Moore, and his representatives, that negotiated the proposed \$16 Million settlement with the Inspira. I therefore have personal knowledge regarding the Settlement and the related negotiations, matters at issue, and competing positions of the parties. I also have personal knowledge as to all other matters set forth in this Declaration.
- 2. I am an attorney at law duly admitted to the Bar of the State of New Jersey, State of New York, and Commonwealth of Pennsylvania and District of Columbia. I am a shareholder

of the Southeastern Pennsylvania and Southern New Jersey regional law firm of Saltz,

Mongeluzzi, Barrett & Bendesky, PC. My personal law practice focuses on the litigation and
trial of medical malpractice, professional negligence, pharmaceutical drugs and medical devices
products liability, civil rights and a broad spectrum of other civil litigation cases. I am a

Certified Civil Trial Attorney by the Supreme Court of New Jersey. I am also a Fellow of the
American College of Trial Lawyers, a Certified Civil Pre-Trial and Trial Advocate of the
National Board of Trial Advocates, and a Fellow of the Advisory Board of Litigation Counsel of
American.

3. I am admitted *pro hac vice* in the *NECC* MDL in connection with my firm's representation of thirty-six individual New Jersey claimants who received one or more injections of NECC's allegedly contaminated methylprednisolone acetate ("MPA") at one of the following Southern New Jersey healthcare facilities: (a) Inspira's Vineland and Elmira healthcare facilities (which facilities were formerly known respectively as South Jersey Regional Medical Center and South Jersey Hospital- Elmira<sup>1</sup>); and/or (b) Premier Orthopaedic Surgical Center, Inc.'s ambulatory surgical center facility in Vineland, New Jersey. My clients include individuals who developed fungal meningitis and other spinal fungal infections. Some have had very long term hospitalizations and complications as a result of the contaminated MPA injections.

<sup>&</sup>lt;sup>1</sup> At the time the contaminated MPA was administered in 2012, Inspira Health Network, Inc. was known as "South Jersey Health System, Inc.", and its medical facilities in Vineland and Elmer, New Jersey, were owned and operated by a subsidiary named "South Jersey Hospital, Inc." In 2013, South Jersey Health System became a part of the "Inspira Health Network" in connection with a consolidation of southern New Jersey community hospitals.

<sup>&</sup>lt;sup>2</sup> Premier Orthopaedic Surgical Center is owned by many of the doctors associated with Premier Orthopaedics and Sports Medicine Associates of Southern New Jersey, LLC. ("Premier Ortho"), which is also named in many suits in the MDL due to the role of Premier Ortho's Dr. Kimberly Smith-Martin in prescribing and administering NECC's MPA to patients at Inspira's two facilities. For ease of reference, "**Premier**" used further in this Declaration shall mean and refer to both Premier Orthopaedic Surgical Center and Premier Ortho.

- 4. I have been appointed by the NECC PSC to serve as co-chair of the PSC's New Jersey State Claimants Subcommittee designated to prosecute the state specific claims of NECC's victims injured in New Jersey ("NJ-PSC Subcommittee").<sup>3</sup> In that capacity, I was entrusted and tasked to coordinate and manage the investigation and prosecution of the New Jersey claimants' cases in the MDL against New Jersey clinical entities and various individual New Jersey health care providers who were involved in the selection, prescription and/or administration of NECC's preservative free MPA that was the subject of the NECC MDL. New Jersey was one of the states hit hardest by NECC's recalled preservative free MPA. Claimants suing from New Jersey comprise one of the largest plaintiff groups in the NECC MDL.
- 5. I and other members of the NJ-PSC Subcommittee have been and are cooperatively investigating the liability of Inspira and Premier relating to the contaminated MPA injections. Among other things, we have obtained and reviewed records relating to NECC and NECC's interactions and dealings with Inspira and Premier from the following sources: government agencies and Congressional investigative committees; documents that Inspira and Premier produced to the PSC pursuant to subpoenas; and documents that NECC's Trustee made available to the OCC, PSC and the NJ PSC subcommittee for specific use in connection with the Inspira mediation before Professor Eric Green, Esq. Members of the NJ-PSC Subcommittee and I have also consulted with various experts in the fields of drug compounding, anesthesia, pain management, infectious diseases, ambulatory surgical facility management, and clinical formulary management. Based upon these investigative efforts, I believe that I and members of

<sup>&</sup>lt;sup>3</sup> Members of the NJ PSC Subcommittee include attorneys from the law firms of Andrews & Thornton (which firm serves also as an OCC co-chair member representative), Cohen Placitella & Roth (which firm serves also as an OCC co-chair member representative), Golomb & Honik, PC, Hoffman DiMuzio, Law Offices of Jeffrey M. Keiser, The Orlando Firm (also a member of the PSC) and Soloff & Zervanos, PC.

the NJ-PSC Subcommittee developed sufficient information, knowledge and resources to prosecute the cases against Inspira and Premier on behalf of NECC MPA tort victims. We have obtained and/or are able to obtain required Affidavits of Merit as to New Jersey health care providers and facilities targeted by MDL plaintiffs. The information the NJ PSC Subcommittee has developed enables me to identify, understand and weigh the various liability and damages factors involved in the NECC litigation to both meaningfully participate in mediation with Inspira Health Network's representatives on behalf of injured plaintiffs and to make the statements and offer the professional opinions contained in this declaration.

- 6. During the second half of 2013, Inspira Heath Network agreed to participate in a mediation program offered by the OCC, the PSC and the Trustee. While Inspira chose not to enter into the mediation program established by the MDL Court, it nonetheless agreed to mediate privately with the OCC, PSC and Trustee before Professor Eric Green, who was designated by Judge Zobel as the lead mediator in the MDL's Court's mediation program. Judge Zobel was apprised of the Inspira private mediation and was periodically provided status reports on its progress.
- 7. The following claimants' negotiating committee represented the interests of the injured New Jersey NECC claimants in the mediation with Inspira: (a) the NECC Trustee, Paul D. Moore, Esq. (in addition to himself, Mr. Moore was also represented by his attorneys Michael R. Gottfried and Jeffrey D. Sternklar); (b) member representatives of the OCC (Anne Andrews, Esq., Michael Coren, Esq., Harry Roth, Esq. and John Thornton, Esq.; (c) counsel for the OCC (David Molton, Esq.); (d) members of the PSC (Patrick T. Fennell. Esq., Thomas Sobol, Esq., the PSC's Lead Counsel, and Mark Zamora, Esq.); and (d) members of the NJ-PSC

Subcommittee (including myself, Jeffrey P. Fritz, Esq., Ernest L. Alvino, Esq., Mary T. Gidaro, Esq., Jeffrey M. Keiser, Esq., and Steven Resnick, Esq.).

- 8. Under the auspices of the mediator, Professor Green, Inspira and the claimant's negotiation committee held numerous conference calls starting in the fall of 2013 and continuing until June, 2014. During those calls, the parties exchanged demographic information on the claims, including nature and incidence rates of various categories of claims corresponding closely to the Center for Disease Control ("CDC") categories, but modified to reflect the unique experience among the New Jersey exposed population. The good faith exchange of information permitted the mediation parties to agree upon the number of patients who were treated at Inspira's two facilities, that is, 213 individual patients, as well as the distribution of disease and injury among the group of Inspira patients. Inspira also provided pertinent financial and insurance information. As part of this pre-mediation session process, the parties submitted to the mediator and exchanged among themselves confidential mediation memoranda outlining each side's positions on legal claims, injuries and defenses. Accordingly, each side was able to proceed into mediation fully aware of each side's position and the basis for that position and to assess the strengths and weakness of their respective positions.
- 9. On July 2, 2014 and July 24, 2014, lengthy mediation sessions were held in New York City.

<sup>&</sup>lt;sup>4</sup> As part of its epidemiological investigation into the cause and extent of the 2012 fungal infection outbreak, the CDC established a set of case definitions to determine disease incidence rates associated with NECC's contaminated drugs: (1) meningitis; (2) meningitis and paraspinal/spinal infection; (3) stroke without lumbar puncture; (4) paraspinal/spinal infection; (5) peripheral joint infection; (6) paraspinal/spinal infection and peripheral joint infection; and (7) death. Since unlike other states no acute deaths in New Jersey related to the outbreak had occurred and been reported to the CDC or Inspira, for global negotiation purposes an alternative seventh category was created: "No CDC Category". This category captured "contaminated MPA exposed only" cases as well cases where the claimant underwent diagnostic testing such as lumbar puncture and/or an MRI but had no positive findings for infection.

- 10. During the first session on July 2, counsel representing plaintiffs made presentations concerning some of their clients to illustrate the claims and the breadth of injuries involved. Following that, under the mediator's auspices the parties discussed at length the strengths and weaknesses of the liability case against Inspira, which liability Inspira steadfastly denied existed. The strengths and weaknesses of the liability cases against various other actors involved in the NECC cases, many of whom were co-defendants named by the plaintiffs, were also discussed. It was made known to the claimants' negotiation team that Inspira had issues with its insurance carriers over coverage that bore upon the negotiations.
- 11. The settlement negotiations were at times contentious. They were throughout very hard fought and conducted on an arm's-length basis. Professor Green at all times was actively involved in the process, ably forcing the various factions to dispassionately, logically and realistically reexamine their positions, authorities and facts, and to consider things that one side or the others previously had not considered. His efforts brought about movements and realistic bargaining on each side.
- 12. The mediation session concluded during the evening of July 24, 2014, with the parties reaching an agreement on the essential financial terms pursuant to which Inspira and its insurers would contribute \$16 million to the settlement fund. Following that, counsel for the OCC, PSC and Trustee negotiated the terms of the written settlement agreement that is now before the Court. I and OCC's co-chair Michael Coren, also a member of the New Jersey Bar, negotiated the terms of the Agreement's joint tortfeasor release provisions, to assure that claims against other potentially responsible parties, including Premier, were preserved.
- 13. Following the mediation and while the Plan documents were being prepared and finalized, members of the OCC, MDL PSC and NJ-PSC subcommittee met and conferred on

numerous occasions to develop and agree upon a claims resolution facility and distribution matrix for the portion of the Inspira settlement specifically earmarked and allocated under the proposed plan of reorganization (the "Plan") to claimants administered contaminated NECC drugs at Inspira. We modeled the claims resolution facility upon the proposed Chapter Plan's Tort Trust's claims resolution facility. We all agreed that the Plan's Tort Trust distribution matrix should serve as the basis for distribution with modifications (via a supplementary matrix) designed to provide compensation reflecting the range and extent of injuries of the Inspira claimants sharing this allocated fund. The process of reaching agreement was consensus-driven and reflects the input and efforts of numerous NJ-PSC subcommittee members, members of the PSC and members of the OCC.

### THE REASONABLENESS OF THE INSPIRA SETTLEMENT

14. If allowed by this Court, the Plan will provide the NECC estate with an amount projected to exceed \$200 million. In this regard, the Plan contemplates court approval of numerous settlements of various claims and disputes between and among the NECC estate, certain of NECC's contractors and their insurance companies, NECC's product testing laboratory, various clinics and hospitals that administered contaminated MPA and personal injury claimants, one of which is the \$16 million proposed settlement with Inspira and its insurers. The \$16 million Inspira Settlement provides that fifteen percent (15%) of it will be distributed as part of the general NECC bankruptcy estate pursuant to a Chapter 11 Plan with the remaining eighty-five percent (85%) allocated to go into a separate Inspira Claims Facility established under the Plan to make compensation payments exclusively to NECC personal injury claimants who were administered contaminated NECC drugs at an Inspira facility in New Jersey. As mentioned, there were according to Inspira's records 213 individuals administered NECC

preservative free MPA drawn from vials in the three recalled lots. The allocation between the general plan distribution and the segregated fund for Inspira patients reflects recognition of the number of persons with unique claims against Inspira as well as the fact a global settlement must deal with the existence of NECC's and other's contribution claims against Inspira and contribute towards bankruptcy administration expenses

- 15. I believe that the Inspira settlement is fair, reasonable and adequate, and can and should be approved as part of the Chapter 11 approval proceedings for at least the following reasons:
- a. Result: The \$16 million settlement achieves fair, reasonable and adequate value from Inspira for both the NECC creditors in general and especially those creditors who were injured as result of being administered contaminated MPA at Inspira's two New Jersey facilities. In assessing and weighing the value of the claims against Inspira being compromised against the value to the estate and its creditors, I believe the result of the settlement provides a greater recovery to NECC's bankruptcy estate and its creditors than is possible through litigation, and without the corresponding delay, expense and risks associated with any such litigation.
- b. In stating this professional opinion, I have taken into account, on the one hand, the array of injuries suffered by the 213 exposed Inspira patients. Based upon examination and review of numerous Inspira claimants' medical records or reports on their condition the NJ-PSC Subcommittee had available to them, I can inform the Court the claims against Inspira fell into discrete ascertainable categories well matching the CDC's fungal infection outbreak case definition categories, with the exception there were no cases of acute death as occurred in several other states. That said, there was a substantial variance in degree of harm and duration of injury

<sup>&</sup>lt;sup>5</sup> See footnote 4 *supra*.

among the members of the cohort. For example, some of the injury claims were very modest, being no more than having been injected with the contaminated medication and consequentially suffering reasonable and understandable upset and concern lasting many, many months because of the novelty of the outbreak situation, reports of delayed effect onset and the inability of the medical community to definitely state that there was no further risk or concern. A significant number of the Inspira exposed population, however, were much more seriously injured. Many were required to undergo one or more painful lumbar puncture diagnostic/monitoring procedures as well as repeated MRI's and blood tests. Many were diagnosed with fungal infections (meningitis and/or spinal or para-spinal abscesses) which required medical treatment for many months at least; some of these patients are still being treated today, more than two and a half years later. Some of the Inspira patients required surgery to debride abscesses that formed in tissue at or near injection sites. And a good number of the exposed patients were put on long courses of potent antifungal medications. The anti-fungal medications prescribed had terrible side effects and risks and often required hospital stays in order to initiate the treatment. Known side effects associated with these medications (such as disturbing hallucinations, liver or kidney function impairment, rashes and skin eruptions, very painful light insensitivity and long-lasting cognitive impairment) were often reported. In addition there were a number of exceptional injuries among the infected patients, such as a heart attacks and serious neurological disorders. These categories, incidence numbers and variation in degree and duration of harm of the cohort were all taken into account when negotiating the settlement with Inspira and its insurance carriers and agreeing in principle to the \$16 million global number. These were also considered and taken into account in devising the Inspira claims resolution distribution matrix for the Inspira cohort's earmarked fund.

- c. While steadfastly maintaining that it was not legally liable and had numerous valid defenses (which I address below), Inspira and its insurers nonetheless agreed that, in exchange for a non-debtor release and injunction providing them protection against any and all of the numerous competing claims and substantial potential liability relating to NECC's compounded drugs, they are willing to make a very substantial contribution of \$16 million to the NECC estate, . This amount should provide considerable payments to qualified individual Inspira claimants who qualify and make application to the Inspira Claims Resolution Facility for compensation. It also provides a substantial amount of funds for general Plan purposes, particularly other tort claimants not treated in New Jersey by Inspira.
- d. <u>Collectability</u>: The Inspira settlement of \$16 million is a substantial portion of Inspira's entire available insurance coverage. I believe that the settlement amount of \$16 million is an amount that is more than could be secured were the NECC estate and personal injury claimants to succeed in litigation, especially when taking into account the costs and expenses of any such litigation and inevitable appeals. The settlement ensures prompt recovery without the risk of depleting, through years of litigation, judgments among competing claimants that otherwise might exhaust amounts available for competing claimants.
- e. <u>Disputed Liability</u>: The prospects for recovery against Inspira in litigation were and are far from certain. While I and members of the NJ-PSC Subcommittee believe that Inspira's negligence could be proven, the issues of causation and allocation of fault are more difficult issues. An inability to prove proximate causation between Inspira's culpable conduct and the plaintiffs' injuries could raise serious issues that defeat liability entirely. Inspira maintained that it acted reasonably and within applicable standards of care, did not know of

NECC's shortcomings and indeed viewed itself a victim of NECC and the NECC insider's criminal conduct. And, even if successful in proving Inspira's causative contribution to its patients' injuries, there was a more pivotal issue of its comparative fault under New Jersey's comparative fault scheme. More particularly, NECC claimants would need to establish that Inspira was at least sixty percent (60%) at fault in order to have Inspira held jointly and severally liable for any claimant's entire judgment. <sup>6</sup> Thus, the reality of this case is that Inspira's relative fault – while a jury question we believe claimants would likely prevail on – had to be seriously considered and factored into valuing the claims and the likely recovery. Accordingly, in negotiating the Inspira settlement, all parties took into account and considered the nature and degree of other NECC potentially responsible actors' relative fault, including NECC, NECC's employees and officers, Premier's doctors, ARL, Liberty, Victory and Unifirst. Taking these liability factors into account, it is my professional opinion that the Inspira settlement is equitable, fair, reasonable and adequate.

f. Plan Progress/Interests of Creditors: The approval of the Inspira Settlement is essential to the approval of a Chapter 11 plan and, I believe, is clearly in the best interest of the estate's creditors. The victims of the outbreak have already waited for over two and one-half years for compensation, and confirmation of the Plan will allow distributions from the Tort Trust to begin to be made to them. Both the Inspira Settlement and the Chapter 11 eliminate the danger of races to the courthouse and to trial that exist here given the limited amounts of insurance

<sup>&</sup>lt;sup>6</sup> Under New Jersey law, if a party is found to be less than 60% responsible for total damages, it can be held responsible only for payment of that percentage of damages directly attributable to its negligence. N.J.S.A. 2A:15-5.3. Of course there is was also the risk –one we believed remote—that a jury would ascribe no liability against Inspira. Still the risk existed.

coverage and number of potential claims. For the reasons I set forth in this Declaration, I have strongly recommended to each of my firm's clients that they vote in favor of the Plan.

Complexity, Expense, Inconvenience and Delay in Pursuing Litigation. The g. litigation that would be required to be pursued if the Inspira settlement is not approved would be complex, expensive and protracted. Indeed, we know this first hand as I and members of the NJ-PSC Subcommittee litigate in parallel proceedings against Premier defendants, who refuse to even discuss settlement even two and a half years after the event. Under the current MDL case management orders New Jersey claimants trials against Premier will not begin until sometime around early summer of 2016. Before then we anticipate numerous depositions being taken and following that dispositive motions and extensive in limine motion battles. Moreover, any litigation against Inspira likely would be protracted and further delayed by inevitable appeals, such that any recovery for the benefit of tort claimants would be significantly delayed. Absent settlement, Inspira would vigorously contest its liability, all the while reducing the amount of available insurance coverage—its remaining insurance coverage being of the type that defense costs reduce the amount of indemnity coverage available. Therefore, I do not believe that it is in the best interest of the NECC estate or the personal injury claimants to pursue the complex, lengthy, and costly litigation that would be required if the Inspira settlement is not approved. Many of the personal injury claimants are suffering substantial financial hardship as a result of the injuries caused by the contaminated MPA, and they have a compelling need to secure a recovery as soon as possible. The proposed settlement will greatly enhance the likelihood of achieving that goal.

## The Non-Debtor/Third Party Releases are Necessary to Bring About the Inspira Settlement

16. The contemplated Inspira settlement is conditioned upon confirmation of a Plan that provides non-debtor or third party releases, both to contributors as well as certain parties

who are not direct contributors. The scope of these releases is limited to claims arising from contaminated NECC products. These releases will have to be approved by this Court at confirmation (the settlement agreements, by their terms, only become wholly effective upon confirmation of a plan containing such releases). These non-party third party releases are a critical component of the Inspira settlement, particularly with respect to persons and entities who are not directly contributing funds as part of this settlement such as Inspira's directors, officers, employees and insurers. Inspira as a New Jersey non-profit charitable entity has limited liability under New Jersey law, but still remains liable over and above this charitable immunity limit for the negligence of its employees, officers and servants. New Jersey Claimants were all prepared to name as co-defendants Inspira's directors, officers, employees and agents once identified during discovery as having potential responsibility for the contaminated NECC drugs.

Understandably Inspira insisted it would not settle without obtaining full releases of such employees' and agents' liability, as well as the release of any claims against Inspira's insurers arising out of the NECC contaminated drugs.

- them, Inspira and its insurers would not have agreed to pay \$16 million to settle the NECC claims. The amount we obtained reflects Inspira's desire to completely and once and for all put the administration of contaminated NECC drugs to patients at Inspira's facilities behind it and move on. As a direct participant in the settlement negotiations, I understood that it was a *sine qua non* of reaching a settlement that the Plan provide for a channeling injunction and third party releases to enable Inspira to once and for all time put this episode behind it.
- 18. The benefits to the NECC estate from the \$16 million Inspira settlement, the majority of which will flow to the tort claimants and particularly the patients exposed at Inspira's

two New Jersey facilities, is a principal reason why the third party releases are reasonable. Since it is anticipated that personal injury claimants will hold the vast majority of allowed claims, the vast majority of the net proceeds of the Inspira settlement (after payment of allowed administrative expenses and priority claims, if any) will be distributed to personal injury claimants. Moreover, the settlement funds will be distributed in a fair and equitable manner, rather than as a result of a race to the courthouse.

## The Inspira Claims Facility is a Fair and Equitable Means to Distribute the Inspira Settlement.

19. As stated above, following the negotiation of the \$16 million settlement amount, members of the OCC, PSC and NJ-PSC Subcommittee prepared a proposed Inspira Claims Resolution Facility and Supplementary Matrix to handle the distribution of the \$16 million settlement allocated for distribution to Inspira patients only. The matrix and claims procedures are patterned on the National matrix with changes to reflect the Inspira cohort's experience and needs. As part of the process, several proposed claims administrators submitted proposals and were interviewed. On the basis of those interviews and proposals, Edgar C. Gentle, III, Esquire was selected to serve as the Inspira Claims Facility administrator. All of the decisions relating to the claims facility, the claims processes, the supplemental matrix and the claim administrator were made by consensus of the counsel representing Inspira claimants who desired to participate in developing this claim allocation and distribution infrastructure. I believe they are all fair, reasonable, adequate and equitable measures and decisions and should be approved by this Court.

#### **CONCLUSION**

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20. The Inspira settlement provides for an exceptional outcome for creditors and NECC's estate. It provides \$16 million, without the costs, complexity, delay and ultimate uncertainty of litigation. The vast majority of the Inspira settlement amount will inure to the benefit of Inspira personal injury claimants holding allowed claims. In my opinion, the Inspira settlement is fair, reasonable, adequate and equitable and the interests of personal injury claimants is best served by approval of the Inspira settlement.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 28, 2015

Michael F. Barrett, Esq.